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EP 0909952 A2
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(54) Abstract Title
Test strip

(57) A test strip suitable for use in a test device for testing of analyte concentration in a fluid has a base member 2 having a working area 4 to which the fluid is to be applied, containing a reagent which is reactive to the said analyte to produce an electrical signal or a colour change, and a non-working area 8 adjacent to the working area 4. The total thickness of the test member in at least a portion of the non-working area 8 is at least as great as the total thickness in the working area 4. A plurality of strips can be arranged as a stack. Working area 4 typically comprises an electrode plurality in contact with a reagent layer with electrode tracks 12 in the non working area 8 which has high relief ink 10 printed thereon to increase it's thickness. Glucose in blood is typically determined by the strip.

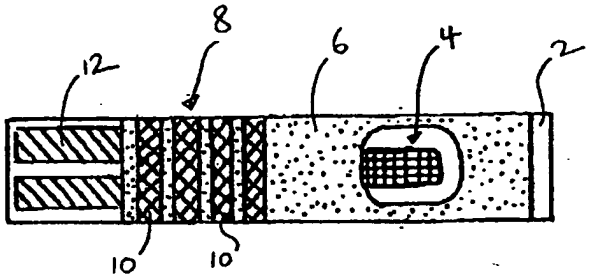

FIG. 1

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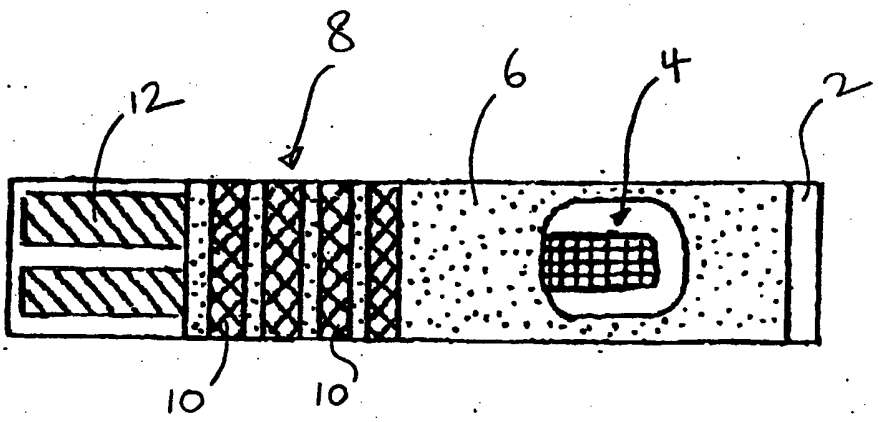

FIG. 1

TEST MEMBER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a test member for measuring the concentration of an analyte in a fluid sample, notably to a test strip for analysing blood glucose or other analytes in bodily fluids. The invention also provides a test device which includes a stack of the test members.

2. Background of the Invention

Diabetics regularly need to test samples of their blood to determine the level of blood glucose. The results of such tests may be used to determine levels of medication needed to treat the diabetes at the time. In one known type of system, disposable sensors are used to test the blood. The sensors typically take the form of test strips which are provided with a reagent material that will react with blood glucose to produce an electrical signal. Conductive tracks on the test strip relay the electrical signal to a meter which displays the result. After a sample of blood has been applied to the test strip and the measurement has been taken, the test strip is disposed of. In order to couple the conductive tracks on a test strip with the meter, the test strip needs to be inserted into a sensor holder prior to the start of testing. The sensor holder has corresponding electrodes which are brought into electrical contact with the conductive tracks of the test strip. Alternatively, the reagent in the test strip may undergo a visible colour change, the magnitude of which is used to determine the analyte concentration in the applied

fluid.

It is known to provide a stack of disposable circular test elements in a cylindrical housing, the stack being urged towards a test station by a spring to form a liquid-proof seal, for example as described in WO 94/10558.

A problem with providing disposable test members in a stack is that the working area to which the fluid sample will be applied can become scuffed, particularly when a compressive force is applied to the stack by a spring.

It is an object of the present invention to provide an improved test member suitable for use in test devices that employ test members in a stack.

SUMMARY OF THE INVENTION

According to an aspect of the present invention there is provided a test member suitable for use in a test device for testing of analyte concentration in a fluid to be applied thereto, the test member comprising a base member having a working area to which the fluid is to be applied, containing a reagent which is reactive to the said analyte to produce an electrical signal or a colour change, and a non-working area adjacent to the working area, wherein the total thickness of the test member in at least a portion of the non-working area is at least as great as the total thickness of the test member in the working area.

By making the non-working area at least as thick as the working area, scuffing or abrasion of the working area in a stack can be reduced. Moreover, if a compressive load is applied to a stack of the test members, this may be spread out over a greater area, thereby reducing the

possibility of compressive damage to the working area.

In a preferred embodiment, at least a part of the non-working area is of greater total thickness than the thickness of the working area. This further reduces the likelihood of damage to the working area by scuffing or abrasion when in a stack. The difference in thickness is preferably from 1 to 20 μm, notably from 5 to 10 μm.

The test member may be of any desired shape for a particular application; however, typically the test member will be an elongate test strip. For convenience hereinafter, the invention will be described with reference to such a test strip. However, it is to be understood that the invention is not limited to this embodiment.

In one embodiment, the reagent is reactive to the analyte to produce a visible colour change. Alternatively, the reagent may react with the analyte to produce an electrical signal which is measured and displayed by a meter. In this embodiment, the working area has electrodes which are electrically connected to electrode tracks in the non-working area, and at least part of the tracks are exposed for connection to electrodes of a meter. The invention will be described hereinafter with reference to this embodiment.

To build up the working area, a plurality of layers are sequentially applied to the base layer, for example by screen printing, typically with curing or drying steps between the application steps. The layers which are printed typically comprise electrode patterns, a reagent layer, and a mesh layer (for spreading out an applied fluid). As a result of the application of these layers,

the working area of a conventional electrochemical test strip is typically about 100 μm thicker than the non-working area, which contains the electrode tracks and, typically, a dielectric layer. A stack of 100 test strips will therefore be about 10 mm thicker in the working area than in the non-working area. In a test strip in accordance with the present invention, at least a part of the non-working area may be made thicker by any suitable means. Suitable means include, for example: a printed relief ink; an applied pad or tape; embossing of the base layer or an intermediate layer; or an extension of the mesh layer from the working area.

The invention also provides a test device which uses the test members. Accordingly, another aspect of the invention provides a test device for testing of analyte concentration in a fluid to be applied thereto, the device including a plurality of test members arranged in at least one stack, each of said test members carrying reagent means for producing an electrical signal or a colour change in response to the concentration of analyte in an applied fluid; wherein each of the said test members comprises a base member having a working area to which the fluid is to be applied, containing the said reagent means, and a non-working area adjacent to the working area, wherein the total thickness of each test member in at least a portion of the non-working area is at least as great as the total thickness of each test member in the working area.

The test members may be held under a compressive load by spring means.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be further described, by way of example, with reference to the following drawing in which:

Figure 1 is a top plan view of a test strip in accordance with the present invention.

DETAILED DESCRIPTION

The exemplified test strip comprises a planar base member 2, in this example of poly(butylene terephthalate) (PBT) (Valox® FR-1 from GE Plastics). The strip is 30 mm x 5.5 mm, and 0.5 mm thick. A working area 4 is of conventional construction, comprising a plurality of electrodes, a reagent layer in intimate contact with the electrodes, and a mesh layer for spreading out a drop of fluid to be received on the working area. Electrode tracks 12, for example of carbon, in the non-working area 8 of the test strip are connected to the electrodes in the working area 4 in known manner. Also in known manner, a dielectric layer 6 is printed around the working area 4 so as to overlie a portion of the electrode tracks 12, leaving just the ends of the tracks exposed for connection to corresponding electrodes on a meter. The layers are applied to the base member as inks, by screen printing. Each ink layer is about 10 to 20 μm thick, and the mesh is about 59 to 67 μm thick. The working area 4 has a total thickness which is about 100 μm thicker than the non-working area 8 up to the dielectric layer 6.

To increase the thickness of parts of the non-working area, a high relief ink 10 has been printed in four strips. The high relief ink has a dried thickness such

that the total thickness of the non-working area to which the high relief ink 10 has been applied is slightly greater than the total thickness of the test strip in the working area 4. Thus, when a stack of such test strips is formed, and a compressive load is applied to the stack by a spring, the working area 4 will not bear all the compressive load. If the test strips are used in a device which requires one strip to be slid out before being used to test analyte concentration in a fluid, scuffing of the test area will be reduced compared to a conventional test strip in which the working area stands proud of the non-working area.

Although the invention has been illustrated with reference to the use of a high relief ink printed in strips, it will be understood that it is not limited to this embodiment. The ink could be printed as a continuous block, and it could entirely surround the working area if desired. Instead of, or in addition to, the high relief ink, other means could also be provided to increase the thickness of the non-working area, for example: an applied pad or tape; embossing of the base layer or an intermediate layer; or an extension of the mesh layer from the working area into the non-working area.

CLAIMS

1. A test member suitable for use in a test device for testing of analyte concentration in a fluid to be applied thereto, the test member comprising a base member having a working area to which the fluid is to be applied, containing a reagent which is reactive to the said analyte to produce an electrical signal or a colour change, and a non-working area adjacent to the working area, wherein the total thickness of the test member in at least a portion of the non-working area is at least as great as the total thickness of the test member in the working area.

2. A test member as claimed in claim 1, wherein the total thickness of the test member in at least a part of the non-working area is greater than the total thickness of the test member in the working area.

3. A test member as claimed in claim 2, wherein the total thickness of the test member in at least a part of the non-working area is from 1 to 20 μm greater than the total thickness of the test member in the working area.

4. A test member as claimed in claim 2, wherein the total thickness of the test member in at least a part of the non-working area is from 5 to 10 μm greater than the total thickness of the test member in the working area.

5. A test member as claimed in any one of the preceding claims wherein the said at least a part of the non-working area includes a printed ink layer.

6. A test member as claimed in any one of the preceding claims wherein the said at least a part of the non-working area includes an adhered tape or pad.

7. A test member as claimed in any one of the preceding claims wherein the said at least a part of the non-working area includes an embossed structure.

8. A test member as claimed in any one of the preceding claims wherein the said at least a part of the non-working area includes a mesh layer.

9. A test member as claimed in claim 8, wherein the said mesh layer is continuous with a mesh layer in the working area.

10. A test member as claimed in any one of the preceding claims, wherein the said reagent produces an electrical signal in response to the concentration of analyte in an applied fluid, the test member having a plurality of electrode tracks for transmitting the electrical signal, the said electrode tracks being exposed on a portion of the non-working area for connection to corresponding electrodes of a meter of a test device.

11. A test member as claimed in any one of the preceding claims, wherein the test member is an elongate test strip.

12. A test member as claimed in any one of the preceding claims, suitable for use in testing for the concentration of glucose in blood.

13. A test member suitable for use in a test device for testing of analyte concentration in a fluid to be applied thereto substantially as herein described with reference to the drawing.

14. A test device for testing of analyte concentration in

a fluid to be applied thereto, the device including a plurality of test members arranged in at least one stack, each of said test members carrying reagent means for producing an electrical signal or a colour change in response to the concentration of analyte in an applied fluid; wherein each of the said test members comprises a base member having a working area to which the fluid is to be applied, containing the said reagent means, and a non-working area adjacent to the working area, wherein the total thickness of each test member in at least a portion of the non-working area is at least as great as the total thickness of each test member in the working area.

15. A test device as claimed in claim 14, wherein the at least one stack of test members is held under a compressive load by spring means.

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Claims searched: All

Examiner: Michael R. Wendt
Date of search: 10 November 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): G1B (BCB); G1N (BPP, BPX, BPMX, BPME)

Int Cl (Ed.7): C12Q 1/00; G01N 27/00, 27/403, 33/487, 33/52, 33/543, 33/558, 33/66, 35/00

Other: Online: EPODOC, WPI, Japio

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	EP 0909952 A2	(MATSUSHITA) e.g. see Figures 1 & 2; Column 6 lines 19 etc.	1
A	WO 99/13100 A1	(ABBOTT) e.g. see Figure 1; page 5 lines 13 etc.	1
A	WO 94/10558 A1	(ENVIROMED) *mentioned in the application* e.g. see Figure 1; Claim 1.	1
A	WO 92/17778 A1	(WILSON) e.g see Figure 1; page 3 line 20 etc.	1
A	US 5282950	(BOEHRINGER) e.g. see Figure 1.	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.